

REMARKS

The present invention relates in part to immunoassay devices comprising elements for the controlled flow, delivery, incubation, separation, washing and other steps of the assay process. The devices of the present invention can provide advantageous capture efficiencies and sensitivities for the assay of plurality of target molecules.

Claims 74-91 are presently pending in the instant application, with claims 74, 79, and 85 amended herein. The amended claims are commensurate in scope with the claims as filed, and are offered solely to assist the Examiner in understanding the claimed invention. No new matter is introduced.

Notwithstanding the foregoing, Applicant expressly reserves the right to pursue subject matter no longer claimed in the instant application in one or more applications which may claim priority hereto. Applicant respectfully requests reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Non Art-Based Remarks

Finality of the Office Action

Applicant respectfully submits that the finality of the present Office Action is premature, as the Examiner has introduced a new ground of rejection that was not necessitated by amendment of the claims, and requests reconsideration of the finality of the Office Action.

According to MPEP § 706.07(a), a second or any subsequent action on the merits in any application should not be made final if it includes a rejection based on newly cited art, and the rejection was not necessitated by applicant's amendment of the claims or submission by applicant of an information disclosure statement under 37 C.F.R. § 1.97(c). In the present application, the Examiner has entered a new rejection based upon Renn *et al.*, U.S. Patent No. 3,966,897. This new rejection was not necessitated by any amendment of the claims or submission of an information disclosure statement by Applicant, but rather by Applicant's arguments in response to the previous art-based rejections of the claims. *See, e.g.,* Paper No. 14, page 3, *Response to Arguments*.

Moreover, in the previous submission by Applicant, an amendment to a single claim was submitted to obviate a rejection under 35 U.S.C. § 112, second paragraph. Not only was this

amendment not the triggering event for entry of the new ground of rejection, the amendment was one that should have been reasonably expected, and thus should not have resulted in a final rejection. *See, e.g.*, MPEP § 706.07(a) ("[a] second or any subsequent action on the merits in any application... should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed.... For example, one would reasonably expect that a rejection under 35 U.S.C. § 112 for the reason of incompleteness would be replied to by an amendment supplying the omitted element").

Because the final rejection of the claims was premature, Applicant respectfully requests that the finality of the previous office action be withdrawn, so that Applicant may receive a full and fair hearing of the issues raised by the Office Action.

Art-Based Remarks

35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 74-80 and 82-86 under 35 U.S.C. §102(b), as allegedly being anticipated by Renn *et al.*, U.S. Patent 3,966,897 ("the '897 patent").

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teaching of the specification. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See also* MPEP §2131.

As described in the instant specification, *e.g.*, on page 5, lines 3-5, the present invention provides devices that "do not use bibulous or porous materials, such as membranes and the like as substrates for the immobilization of reagents or to control the flow of the reagents through the device." Thus, claims 74-84 describe assay devices for detecting a plurality of target ligands in a sample that comprise nonporous surfaces. These surfaces comprise a plurality of discrete capture zones, each of which comprises immobilized receptors capable of binding one or more of the plurality of target ligands of interest. Similarly, claims 85-91 describe assay devices for detecting one or more target ligands in a sample that comprise nonporous surfaces having particles immobilized thereto.

In contrast, the '897 patent discloses devices that rely upon porous media, in which discrete capture zones may be provided. For example, the '897 patent states in column 2, line 51, through column 3, line 16, that a solid "medium," such as a gel, comprises a reagent that reacts with a test substance. This reagent is immobilized within the "medium" to prevent its diffusion. But the test substance diffuses through or across this medium. Thus, in column 3, lines 35-41, the '897 patent states that the "medium" may be "any of the solid media commonly employed for molecular diffusion procedures."

Moreover, column 7, line 64, of the '897 patent, which the Examiner points to with particularity, discloses the use of agarose gel beads, which are placed in "a well of a conventional electrophoresis strip." This "electrophoresis strip" medium is precisely the type of bibulous or porous material that the present invention seeks to avoid. Because the '897 patent does not disclose any assay devices for detecting a plurality of target ligands in a sample that comprise nonporous surfaces having either a plurality of discrete capture zones (instant claims 74-84), or particles immobilized thereon (instant claims 85-91), Applicant respectfully submits that the '897 patent does not teach each and every element of the instant claims.

Furthermore, while the Examiner has acknowledges in Paper No. 14 that claims 74-84 are directed to devices for detecting a plurality of different target ligands, the '897 patent never discloses such devices. For example, again considering column 7, line 64, of the '897 patent, which the Examiner points to with particularity, the devices disclosed comprise a plurality of capture zones, but each is directed to the same target ligand - "detection and analysis of antibodies to gamma globulin." '897 patent, column 7, lines 67-68. Thus, with regard to claims 74-84, the '897 patent also fails to disclose any devices for detecting a plurality of target ligands in a sample.

In an effort to advance prosecution, Applicant has amended the claims herein to clearly indicate that the receptors or particles of the present invention are immobilized to the non-porous surface. As noted in the specification, *e.g.*, on page 25, lines 21-22, and page 26, lines 1-3, receptors and/or particles may be immobilized to a surface by, *e.g.*, electrostatic interactions, hydrogen bonding, hydrophobic interactions, and/or covalent bonds between the receptors or particles and the non-porous surface. This amendment is intended to clearly distinguish the present claims from devices such as those disclosed in the '897 patent, where receptors are

immobilized within a porous medium, and not to a non-porous surface. This amendment is made in order to clarify the claimed subject matter for the benefit of the Examiner, and is not believed to change the scope of the claims.

Because the '897 patent does not disclose every limitation of the claimed invention, no *prima facie* case of anticipation has been established. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) be reconsidered and withdrawn.

Applicant also respectfully traverses the rejection of claims 74-80, 82, and 85-91 under 35 U.S.C. §102(b), as allegedly being anticipated by Grenner *et al.*, U.S. Patent 5,051,237 ("the '237 patent").

As an initial matter, Applicant respectfully requests clarification of the status of the rejection of claims 74-80 and 82 with regard to the rejection. In Paper No. 14, page 3, the Examiner indicates that the prior art-based rejections of claims 74-84 are vacated in view of Applicant's previous submission, clarifying that these claims are directed to devices for detecting a plurality of different target ligands. Presumably, this includes the rejection of claims 74-80 and 82 based on the '237 patent. Nevertheless, the Examiner has maintained the prior rejection of claims 74-80 and 82 based on the '237 patent, stating simply "[s]ee the appropriate paragraph of page 10." Paper No. 14, page 3. While Applicant traverses this rejection below, clarification of the status of these claims is requested.

Applicant respectfully submits that '237 patent fails to disclose any such devices. The Examiner refers to "an assay device having projections (22) and a plurality of discrete reaction zones" (Paper No. 10, page 2), but does not indicate how such projections or reaction zones might be interpreted as discrete capture zones for binding to a plurality of target ligands.

Moreover, the projections (22) of the '237 patent are said to provide "controlled flow of fluid," rather than any structure related to discrete capture zones. Applicants cannot identify any reference in the '237 patent to "a plurality of discrete reaction zones" as the Examiner contends. Rather, the '237 patent refers to a diagnostic assay element for determining a single analyte. *See, e.g.*, '237 patent, column 6, lines 24-26 ("In one embodiment reagent layer 30 comprises an immunocomplex of a fluorescent-labeled antigen and an antibody directed against the antigen" (emphasis added)). Additionally, the Examiner has never indicated why the '237 patent is

believed to disclose particles comprising receptor for a target ligand immobilized to a nonporous surface, as recited by claims 85-91.

In the previous submission, Applicant requested that the Examiner indicate where such disclosure may be found in the cited publication. The Examiner has not responded to this request, stating only that the claims are anticipated, and referring to "the appropriate paragraph of paper 10." Paper No. 14, page 2. Applicant respectfully submits that the Examiner has not carried the initial burden placed on the Examiner to establish a *prima facie* case of anticipation.

Because the '237 patent does not disclose every limitation of the claimed invention, the claims in the instant application, no *prima facie* case of anticipation has been established. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(b) be reconsidered and withdrawn.

35 U.S.C. § 103

Applicants respectfully traverse the rejection of claims 85-91 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Watts *et al.*, U.S. Patent No. 5,437,983 ("the '983 patent").

To establish a *prima facie* case of obviousness, three criteria must be met: there must be some motivation or suggestion, either in the cited references or in knowledge available to the ordinarily skilled artisan, to modify or combine the references; there must be a reasonable expectation of success in combining the references; and the references must teach or suggest all of the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) *See also*, MPEP §2143.

As described above, instant claims 85-91 refer to assay devices comprising claims 85-91 describe assay devices for detecting one or more target ligands in a sample that comprise nonporous surfaces, in which receptor-bearing particles are immobilized to the non-porous surface.

In contrast, while the '983 patent discloses a the use of beads having specific binding pair members for an analyte affixed to their surface, no non-porous surface comprises beads immobilized thereto. Rather, the beads are suspended in a liquid medium for use. *See, e.g.*, '983 patent, column 7, lines 45-67. The Examiner does not indicate where in the '983 patent it is

believed that receptor-bearing particles immobilized to a non-porous surface or, in the alternative, why the skilled artisan might be motivated to modify the teachings of the '983 patent to provide the claimed invention. Applicant respectfully submits that it is the Examiner's initial burden to establish a *prima facie* case of obviousness. See, e.g., *In re Sang-Su Lee*, 277 F.3d 1338, 1343 (2002) ([t]he factual inquiry whether to combine references of record must be thorough and searching. It must be based upon objective evidence of record.... [P]articular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed) (internal citations omitted). The Examiner has not met this burden.

Because the '983 patent does not teach or suggest the instantly claimed invention, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness, and respectfully requests that the rejection be reconsidered and withdrawn.


CONCLUSION

Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Respectfully submitted,

FOLEY & LARDNER

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